

CHECKLIST FOR MICROBIAL CONTAMINATION TEST (MCT)

Validation test		
1.	Total Viable Aerobic Count (Total Aerobic Microbial Count (TAMC) & Total Yeasts and Moulds Count (TYMC)) (aka Suitability of Counting Method)	Method
		<p>Detailed test procedure for validation of MCT</p> <ul style="list-style-type: none"> - Method used (Plate Count, Membrane Filtration or Most-Probable Number (MPN) method). - Preparation of test sample (including neutralizing of preservatives for samples that contain preservatives)
		Result (raw data)*
		<ul style="list-style-type: none"> - Acceptance criteria: Mean count of any test organisms not differing by a factor greater than 2 (50% – 200%)
2.	Test for Specified Microorganism	Method
		Detailed test procedure for validation of Test for Specified Microorganism
		Result (raw data)*
		<ul style="list-style-type: none"> - Spiked microorganisms must be detected

Routine Microbial Contamination Test		
1.	Total Viable Aerobic Count (Total Aerobic Microbial Count (TAMC) & Total Yeasts and Moulds Count (TYMC))	Method
		Detailed test procedure for Total Viable Aerobic Count <ul style="list-style-type: none"> - Method used (Plate Count, Membrane Filtration or Most-Probable Number (MPN) method). - Preparation of test sample (including neutralizing of preservatives for samples that contain preservatives)
		Result (raw data)*
2.	Test for Growth Promoting, Indicative and inhibitory properties of Media	Method
		Detailed test procedure for Growth Promoting, Indicative and inhibitory properties of Media
		Result (raw data)* <ul style="list-style-type: none"> a) Growth Promoting b) Indicative Properties c) Growth Inhibitory
3.	Test for Media Sterility	Method
		Result (raw data)*
4.	Test for Specified Microorganism	Method
		Detailed test procedure for Test for Specified Microorganism
		Result (raw data)*
5.	Preparation of media	Method
		Result (copy of logbook for preparation of media or any relevant document)

*Raw data must include: Name & Strength of product/ media, Batch No of product/media, microorganisms used, date of test started and ended, observation in every interval period, wherever applicable. Applicant must provide actual data

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